DEC 2 8 2000

K003215

510(K) Summary

Disc-O-Tech Medical Technologies, Ltd.
Fixion Intramedullary Nailing System

Company Name
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St. Herzelia
Israel, 46728

Submitter's Name and Contact Person
Jonathan S. Kahan, Esq.
555 Thirteenth Street, NW
Washington, DC 20004
Tel: 202-637-5794
Fax: 202-637-5910

Date Prepared
August, 2000

Trade/Proprietary Name
Fixion™ Intramedullary Nailing System (Fixion IM Nail)

Classification Name
Intramedullary Fixation Rod
21 CFR § 888.3020
Class II

Predicate Devices
1. Fixion Intramedullary Nailing System (K990717) by Disc-O-Tech.

Performance Standards
The following standards were used:
1. The Fixion IM Nail is manufactured from 316L Stainless Steel, which meets the requirements of ASTM F138 - Standard Specification for Stainless steel Bar and Wire for Surgical Implants.
2. The Fixion IM Nail is designed to meet the requirements of ASTM F565 – Standard practice for Care and Handling of Orthopedic Implants and Instruments.

Intended Use
The Fixion™ Intramedullary Nailing system is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, femur and the tibia. It is indicated for use in shaft fractures 5cm below the surgical neck to 5cm proximal to the distal end of the medullary canal.

System Description

The Fixion Intramedullary Nailing System consist of the following main components:
1. The **Nail Implant** is an expandable, sealed, stainless steel, cylindrical, ribbed rod without interlocking holes. The proximal end has a one way valve for inflation. The nail is cap protected.
2. The **Insertion Handle** is a device designed to be connected to the nail's proximal end, and used for the nail insertion. Its distal end has a locking sleeve to prevent relative rotation between the nail and the handle.
3. The **Inflation Device** is a pump, which rotation of its handle delivers saline into the nail. The pump pressure gauge indicates the inflation pressure. This action causes the nail's expansion and abutment to the bone medullary cavity.

In addition the system consists of a removal kit including a removal adapter, a slide hammer and a slide hammer adapter and a cap driver.

Once the nail is positioned within the medullary canal, rotation of the pump handle allows for nail diameter increase to its intended diameter under x-ray and controlled pressure.

Substantial Equivalence
The Fixion IM Nail is substantially equivalent to the Fixion IM Nail cleared for marketing under 510(k) K990717.
The modified Fixion IM Nail has the following similarities to that which previously received 510(k) concurrence:

- Have the same intended use
- Have the same operating principles
- Incorporate the same design
- Incorporate the same materials

The nail and the insertion kit have the same packaging and sterilization, using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2000

Mr. Johnathan S. Kahan, Esq.
Disc-O-Tech Medical Technologies, LTD.
c/o Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K003215
Trade Name: Modification of Fixion Intramedullary Nailing System (Fixion IM Nail)
Regulatory Class: II
Product Code: JDS
Dated: October 13, 2000
Received: October 13, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): _____

Device Name: Fixion™ Intramedullary Nailing System (Fixion™ IM Nail)

Indication for Use: The Fixion™ Intramedullary Nailing system is intended for use in the fixation of long bone fractures, including diaphyseal fractures in the humerus, femur and the tibia. It is indicated for use in shaft fractures 5cm below the surgical neck to 5cm proximal to the distal end of the medullary canal.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(per 21 CFR 801.109)

OR

Over the Counter Use _____

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003215